DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

October 24, 2014

Wright Medical Technology, Incorporated
Ms. Val Myles
Regulatory Affairs Specialist I
1023 Cherry Road
Memphis, Tennessee 38117

Re: K141714
Trade/Device Name: PRO-TOE® X-Flex Hammertoe Fixation System
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth or threaded metallic bone fixation fastener
Regulatory Class: Class II
Product Code: HTY
Dated: October 13, 2014
Received: October 14, 2014

Dear Ms. Myles:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Lori A. Wiggins -S

for
Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement on last page.

510(k) Number *(if known)*

K141714

Device Name
PRO-TOE® X-Flex Hammertoe Fixation System

Indications for Use *(Describe)*
The PRO-TOE® Hammertoe Fixation Systems are indicated for the fixation of osteotomies and reconstruction of the lesser toes following correction procedures for hammertoe, claw toe, and mallet toe.

Cannulated Implants in the PRO-TOE® Hammertoe Fixation Systems, with the exception of the PRO-TOE® X-FLEX, can be used with Implantable K-wires for the delivery of implants or the temporary stabilization of outlying joints (e.g. MTP Joint).

The Implantable K-Wires are indicated for use in fixation of bone fractures, for bone reconstructions, and as guide pins for insertion of other implants. Additionally, Implantable K-Wires are indicated for the fixation of osteotomies and reconstruction of the lesser toe following correction procedures for hammertoe, claw toe, mallet toe, and metatarsophalangeal joint instability.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

Headquarters
Wright Medical Technology, Inc.
1023 Cherry Road
Memphis, TN 38117
901 867 9971
wmt.com

WRIGHT
FOCUSED EXCELLENCE

510(K) SUMMARY

In accordance with the Food and Drug Administration Rule to implement provisions of the Safe Medical Devices Act of 1990 and in conformance with 21 CFR 807.92, this information serves as a Summary of Safety and Effectiveness for the use of the PRO-TOE® X-Flex Hammertoe Fixation System.

1. Submitted By:

Wright Medical Technology, Inc.
1023 Cherry Road
Memphis, TN 38117

Date: October 17, 2014

Contact Person:

Val Myles
Regulatory Affairs Specialist II
Office (901) 290-5162
Fax (901) 867-4190

2. Proprietary Name: PRO-TOE® X-Flex Hammertoe Fixation System

Common Name: Smooth or threaded metallic bone fixation fastener

Classification Name and Reference: 21 CFR 888.3040- Class II

Device Product Code, Device Panel: HTY - Orthopedic

3. Predicate Device:

- PRO-TOE™ VO Hammertoe Implant System (K101165 & K120645)
- MMI Smart Toe® Hammertoe Implant (K070598)
- WMT Implantable K-Wires (K132895 & K140148)
- Solana Surgical FuseForce Implant System (K124045)

4. Device Description

The PRO-TOE® X-FLEX Hammer Fixation System is a super-elastic, nitinol device which provides active compression across the proximal interphalangeal joint (PIPJ). Unlike competitive nitinol devices on the market, the PRO-TOE® X-FLEX may be stored at room temperature, eliminating the need for freezer storage.

The device is offered in 3 sizes both available in 0° and 10° angulations. The implant is provided sterile and pre-packaged with a K-wire and Pusher instrument. The Pusher instrument is a polycarbonate molded component which is used to perform the final seating of the implant to a pre-determined depth.

5. Intended Use

The PRO-TOE® Hammertoe Fixation Systems are indicated for the fixation of osteotomies and reconstruction of the lesser toes following correction procedures for hammertoe, claw toe, and mallet toe.

Cannulated Implants in the PRO-TOE® Hammertoe Fixation Systems, with the exception of the PRO-TOE® X-FLEX, can be used with Implantable K-wires for the delivery of implants or the temporary stabilization of outlying joints (e.g. MTP Joint).

The Implantable K-Wires are indicated for use in fixation of bone fractures, for bone reconstructions, and as guide pins for insertion of other implants. Additionally, Implantable K-Wires are indicated for the fixation of osteotomies and reconstruction of the lesser toe following correction procedures for hammertoe, claw toe, mallet toe, and metatarsophalangeal joint instability.

6. Technological Characteristics Comparison

The PRO-TOE® Hammertoe Fixation System was originally cleared in K101165 as a V-shaped, open-approach (VO) hammertoe fixation system consisting of implants fabricated from stainless steel (ASTM F138) and available in 2 sizes. Implants fabricated from titanium alloy (ASTM F136) as well as three additional size options were added to the system in K120645, for a total of 5 size options available in both stainless steel and titanium alloy. The PRO-TOE® X-Flex Hammertoe Fixation System and the legally marketed predicate PRO-TOE™ VO Hammertoe Implant System have similar indications and intended use. The PRO-TOE® X-Flex Hammertoe Fixation System and the legally marketed predicate MMI Smart Toe® Hammertoe Implant both use the same material, Nitinol. The modification to the system includes a change in geometry, a change in the material to Nitinol and a device specific instrument for performing the final seating of the implant by allowing the surgeon to maintain proper rotational alignment.

7. Substantial Equivalence- Non-Clinical Evidence

Performance testing including static and fatigue bend testing as well as localized corrosion resistance testing supports the substantial equivalence of the subject device to the predicate device and shows that no new worst-case devices are introduced in this system. The safety and effectiveness of the PRO-TOE® X-Flex Hammertoe Fixation System is adequately supported by testing, substantial equivalence information, materials information, and comparison of design characteristics provided within this premarket notification.

8. Substantial Equivalence- Clinical Evidence

N/A

9. Substantial Equivalence- Conclusions

The design characteristics of the subject devices do not raise any new types of questions of safety or effectiveness. From the evidence submitted in this 510(k), the subject devices can be expected to perform at least as well as the predicate systems and are substantially equivalent.